Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Determining if your medical device should be in the Australian Register of Therapeutic Goods (ARTG)

Guidance to understand if your medical device product should be in the ARTG.

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Purpose

The ARTG is Australia's public database of therapeutic goods. Most medical devices need registration, but some don’t.

Four reasons your product might not need to be on the register:

- not a medical device
- not a therapeutic good
- an 'excluded good'
- an 'exempt medical device

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Regulations 2002

Not a medical device

Your product might be a medical device if it’s used for:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement, or modification of the anatomy or of a physiological process
- control of conception.

Your product may also be a medical device if it is an accessory to any product as described above.

The definition of a medical devices is in Section 41BD of the *Therapeutic Goods Act 1989*.

Not a therapeutic good

Even if your product is **not** a medical device, it may still be another type of therapeutic good.

Use the '*Is my product a therapeutic good?*' tool to work this out.

Excluded vs exempt

Exempt

Does not need to be on the ARTG but may need to comply with certain conditions.

Excluded

Does not need to be on the ARTG and has no conditions that need to be met.

Excluded

Our regulatory framework excludes some products. In this case, you don't need to include it on the ARTG.

Examples include:

- adhesive removers relating to colostomy and ileostomy
- incontinence pads
- ear candles
- menstrual pads other than tampons and menstrual cups.

For more information, refer to excluded goods orders, determinations and specifications.

Exempt

Some therapeutic goods are exempt from needing to be on the ARTG.

These include:

- custom-made medical devices, or
- Class 1, 2, 3 in-house IVDs (subject to certain conditions).

For the complete list of exempt medical devices, refer to the:

- Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 4 (Part 1 and 2) - Exempt devices

Your responsibility

As a medical device sponsor you are responsible for checking your device is on the ARTG. If your product is incorrectly included, you should request cancellation of the ARTG entry.

To cancel an entry, you can do this by either:

- using the TBS portal or
- completing a paper-based form.

We review ARTG entries for products that we expect may not be therapeutic goods. Our team will get in touch with sponsors if we notice an incorrect ARTG entry.

Contact us

If you have any questions, contact us:

- Email devices@tga.gov.au
- Phone 1800 141 144

More information

- Medical device regulation basics

Topics: Australian Register of Therapeutic Goods (ARTG)

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Web content simplified to improve readability.

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